

## REMARKS

The Office Action of January 21, 2011, has been carefully reviewed, and in view of the above amendments and the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

In the above Office Action, claims 1-21 were rejected under 35 U.S.C. § 103(a) as being anticipated by *Cook* (U.S. Patent No. 4,637,396) in view of *Fina* (U.S. Patent No. 4,911,163). For at least the following reasons, Applicants respectfully traverse these rejections.

### Claim 1

As set forth above, claim 1 has been amended to recite that "said inner catheter is withdrawn from said outer catheter after the catheter assembly has been placed at a target site, and a procedure catheter is then inserted into said outer catheter, which remains at the target site." As explained in greater detail in the instant specification, the catheter assembly of claim 1 utilizes the outer catheter and inner catheter together as a guiding catheter to reach a target site. Thereafter, the inner catheter is removed from the outer catheter and a procedure catheter, for example a balloon catheter, is inserted into the outer catheter which remains *in situ* at the target site. See, U.S. Publication No. US2007/0149927, Paragraphs [0125]-[0127].

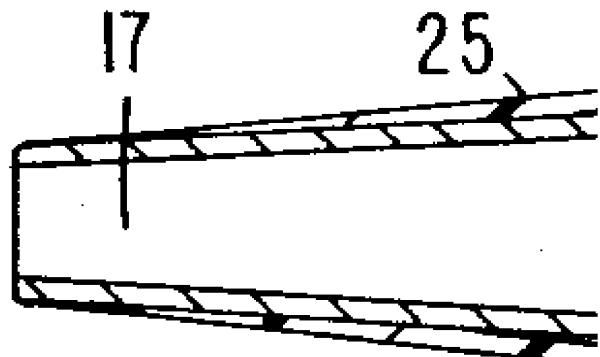
The primary reference relied upon by the Examiner, *Cook*, is directed to a balloon catheter 10 including a catheter tube 11 and a flexible inner member 13. A balloon 12 is disposed coaxially about the inner member 13. Further, the proximal end of the balloon 12 is fixed and sealed to the distal end 16 of the catheter tube 11

and the distal end of the balloon 12 is fixed and sealed to the distal end 18 of the inner member 13. *Cook* thus discloses a conventional balloon catheter, the inner member 13 of *Cook*'s catheter being fixed to the outer tube 11 through the balloon 12.

The Examiner maintains that the catheters of *Cook* are capable of being disengaged and removed from one another. Applicants respectfully submit that while such destruction of *Cook* may be possible, it is certainly not suggested by *Cook*. *Cook* is intended to function as a sealed unit having a pressure seal at the joints 46 and 53 (Col. 4, lines 11-14) noted by the Examiner. Removal of the cap 46 as suggested by the Examiner would break the intended seal. Further, as cautioned by the Federal Circuit, where a modification of the prior art device would render such device inoperable for its intended purpose, the mere fact that the prior art device could be so modified would not have made the modification obvious. In re Gordon, 221 USPQ 1125, 1127 (Fed. Cir. 1984). As such, Applicants respectfully submit that separation of the tubes of as proposed by the Examiner would not be an obvious modification since *Cook* would not operate as intended once the balloon is separated from the inner member 13.

Moreover, *Cook* does not disclose or suggest that catheter 11 or the balloon 12 is intended to receive a further device once or if the inner member were to be removed. That is, *Cook* does not suggest that inner member is withdrawn from balloon 12/catheter tube 11 after the catheter has been placed at a target site or that a further procedure catheter is then inserted into balloon 12/catheter tube 11.

Still further, the Examiner appears to rely on the illustration of Figure 1 in *Cook* for supporting the contention that the inner catheter protrudes from the outer catheter with the distance of no more than 10mm. Applicants respectfully traverse this interpretation as being contrary to the teaching of *Cook*. In particular, referring to Col. 2, lines 43-45, *Cook* discloses that the ends of the balloon are tapered at points 25 and 26 to a smooth transition with the outer surface of the plastic tip 19. As such, the accompanying portion of Figure 1 appears to suggest, at best, that the balloon 12 and the tip 19 terminate coextensively since the line representing the balloon 12 clearly extends to the end of the tip and is thus causing the thickening of the line work. Accordingly, Applicants contend that *Cook* does not suggest an inner catheter protruding from an outer catheter.



The Examiner concedes that *Cook* does not disclose the locking and removable inner catheter of the claimed invention. *See*, Office Action of January 21, 2011, Page 3, last paragraph. Accordingly, the Examiner further relies upon *Fina*, for disclosing an assembly of an inner balloon catheter 1 and an outer balloon catheter 7. However, *Fina* does not disclose or suggest an inner catheter hub formed at a proximal end. *Fina* discloses a screw connection 19 which is used to attach a syringe to the proximal end of the conduit 22. Col. 5, lines 62-63. More over, *Fina* discloses that the inner catheter 1 is clamped and the proximal portion is cut off -- thus negating any possibility of having an inner catheter hub formed at a proximal end. *See*, *Fina*, Col. 5, lines 32-36.

Accordingly, Applicants submit that amended claim 1 is not rendered obvious by the cited prior art.

### **Claim 22**

Newly added claim 22 recites that the inner catheter is longer than the outer catheter. The cited prior art fails to disclose or provide any teaching for having the inner catheter be longer than the outer catheter.

### **Claims 24 and 27**

Newly added claims 24 and 27 recite that the outer catheter is defined by a continuous and integral tube. In contrast, the alleged outer catheter in *Cook* is comprised of a catheter tube 11 and the balloon 12. Thus, it is neither continuous nor integral.

### **Claim 25**

Newly added claim 25 is directed to a catheter system comprising, *inter alia*, an outer catheter body comprising at least an inner layer, an outer layer, and a reinforcing layer interposed therebetween, wherein said inner layer, outer layer and reinforcing layer extend an entirety of the given length of said outer catheter body. In *Cook*, the Examiner relies upon the catheter tube 11 and the balloon 25 as corresponding to the claimed outer catheter, however, only the balloon 25 has a multi-layer construction. Thus, the layers in *Cook* do not extend an entirety of the length of the outer catheter.

Claim 25 further recites, in addition to an outer catheter and an inner catheter, that the catheter system includes a procedure catheter. None of the cited prior art suggests such a system.

Claim 25 also recites that a length of said inner catheter is greater than a length of said outer catheter such that, when said outer catheter hub and said inner catheter hub are engaged with each other, a distal end of said inner catheter protrudes from a distal end of said outer catheter by a distance of no more than 10 mm. As explained above, *Cook* does not disclose or suggest that the inner member 13 is longer in length than the combined catheter 11/balloon 25 and Figure 1 of *Cook* does not support an interpretation that the inner catheter protrudes from the outer catheter.

Claim 25 also recites that after the catheter assembly has been placed at a target site, said inner catheter is removed from said outer catheter and the procedure catheter is then insertable into said outer catheter which remains at the target site. None of the cited prior art suggests such a system.

Accordingly, Applicants respectfully submit that claim 25 is not rendered obvious by the cited prior art.

The dependent claims define additional distinguishing aspects associated with the claimed invention. Since these dependent claims depend from an allowable independent claim, a detailed discussion of the additional distinguishing features recited in these dependent claims is not set forth at this time.

## CONCLUSION

In view of the above amendments and remarks, Applicants respectfully submit that the claims of the present application are now in condition for allowance, and an early indication of the same is earnestly solicited.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference would be helpful in resolving any remaining issues pertaining to this application; the Examiner is kindly invited to call the undersigned counsel for Applicant regarding the same.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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By: /WLWeinstein/  
Wendi L. Weinstein  
Registration No. 34456

**Customer No. 21839**  
703 836 6620